COMMISSIONER FOR PATENT
UNITED STATES PATENT AND TRADEMARK OFFIC
WASHINGTON, D.C. 2023 I

David T. Read Acting Director Health Assessment Policy Staff, CDER Food and Drug Administration 1451 Rockville Pike, HFD-7 Rockville, MD 20852 DEC 19 2002

Dear Mr. Read:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 5,565,467. The application was filed on January 18, 2002, under 35 U.S.C. § 156.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)872-9411 (facsimile).

Karin Ferriter

Senior Legal Advisor

Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: David J. Levy Ph.D, Patent Counsel

GlaxoSmithKline

Corporate Intellectual Property Dept. Five Moore Drive, PO Box 13398 Research Triangle Park NC 27709-3398

RE: Dutasteride Docket No. 02E-0100